

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC,	)	
BESINS HEALTHCARE INC., and BESINS	)	
HEALTHCARE LUXEMBOURG SARL,	)	
	)	
Plaintiffs,	)	C.A. No. _____
	)	
v.	)	
	)	
DR. REDDY'S LABORATORIES, LTD. and	)	
DR. REDDY'S LABORATORIES, INC.,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiffs Unimed Pharmaceuticals, LLC (“Unimed”), Besins Healthcare Inc. (“Besins”), and Besins Healthcare Luxembourg SARL (“Besins Luxembourg”) (collectively “Plaintiffs”) allege as follows for their complaint against defendants Dr. Reddy’s Laboratories, Ltd. (“DRL, Ltd.”) and Dr. Reddy’s Laboratories, Inc. (“DRL, Inc.”) (collectively “DRL” or “Defendants”).

**THE PARTIES**

1. Plaintiff Unimed Pharmaceuticals, LLC, which is a wholly-owned subsidiary of AbbVie Inc., is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

2. Plaintiff Besins Healthcare Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 607 Herndon Parkway, Suite 110, Herndon, Virginia 20170.

3. Plaintiff Besins Healthcare Luxembourg SARL is a Luxembourgian company with its principal place of business at 2-8 rue Julien Vesque, L-2668 Luxembourg.

4. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is an Indian company with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, Telangana, India.

5. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a New Jersey company with its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

### **NATURE OF THE ACTION**

6. This is an action for infringement of U.S. Patent No. 6,503,894 ("the '894 Patent"), titled "Pharmaceutical Composition and Method for Treating Hypogonadism"; U.S. Patent No. 8,466,136 ("the '136 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,466,137 ("the '137 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,466,138 ("the '138 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,486,925 ("the '925 Patent"), titled "Testosterone Gel and Method of Use," U.S. Patent No. 8,729,057 ("the '057 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,741,881 ("the '881 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,754,070 ("the '070 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 8,759,329 ("the '329 Patent"), titled "Testosterone Gel and Method of Use"; U.S. Patent No. 9,125,816 ("the '816 Patent"), titled "Pharmaceutical Composition and Method for Treating Hypogonadism"; and U.S. Patent No. 9,132,089 ("the '089 Patent"), titled "Pharmaceutical Composition and Method for Treating Hypogonadism" (collectively "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208620, which was submitted by Dr. Reddy's Laboratories, Inc. on behalf of Dr Reddy's Laboratories, Ltd. to the U.S. Food and Drug Administration ("FDA") for approval to market a

generic version of AbbVie's AndroGel<sup>®</sup> (testosterone gel) 1.62% (DRL's "Generic AndroGel<sup>®</sup>"). This submission constitutes an act of infringement under 35 U.S.C. § 271(e)(2) that is subject to the provisions of the Hatch Waxman Act.

### **SUBJECT MATTER JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

### **PERSONAL JURISDICTION**

10. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of their ANDA, as set forth below, and for other reasons that will be developed and presented to the Court if personal jurisdiction is challenged.

11. On information and belief, DRL, Inc. and DRL, Ltd. previously availed themselves of this forum by filing lawsuits in this judicial district as a plaintiff, including but not limited to *Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. v. Fresenius Kabi USA, LLC*, 15-cv-714-UNA (D. Del. 2015).

12. On information and belief, DRL, Inc. is a wholly-owned subsidiary of DRL, Ltd. and part of DRL's business in delivering medicines across the U.S.

13. On information and belief, DRL, Ltd. and DRL, Inc. intend to sell DRL's Generic AndroGel<sup>®</sup> through retail drug outlets in Delaware.

14. On information and belief, DRL, Ltd. directs the activities of DRL, Inc., and is directly responsible for sales of DRL products to customers in Delaware, from which DRL, Ltd. derives substantial revenue.

15. On information and belief, DRL, Ltd., directly or through related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over DRL, Ltd. in Delaware on the basis of general jurisdiction.

16. On information and belief, DRL, Ltd. develops and manufactures pharmaceutical products for the United States market, and has developed and manufactured such products, including generic versions of Vidaza<sup>®</sup>, Dacogen<sup>®</sup>, and Lipitor<sup>®</sup>, which are among DRL's major pharmaceutical products according to its annual reports. On information and belief, DRL, Ltd. derives substantial revenue from the sale of products to customers in Delaware.

17. On information and belief, DRL, Inc., directly or through related companies, has engaged in substantial and continuous contacts with Delaware which satisfy due process and confer personal jurisdiction over DRL, Inc. in Delaware on the basis of general jurisdiction.

18. On information and belief, and consistent with their practice with respect to other generic products, DRL, Inc. and DRL, Ltd. acted in concert to prepare and submit ANDA No. 208620.

19. On information and belief, DRL, Inc. and DRL, Ltd. sent to Plaintiffs a letter dated October 27, 2015 (the "Notice Letter") stating that ANDA No. 208620 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale, or importation of DRL's Generic AndroGel<sup>®</sup> before the expiration of the patents-in-suit. The act of sending this letter to AbbVie Inc., a Delaware corporation, and Besins Healthcare Inc.,

also a Delaware corporation, confers personal jurisdiction over DRL, Inc. and DRL, Ltd. in Delaware on the basis of specific jurisdiction.

20. As further evidence of personal jurisdiction, DRL, Inc. and DRL, Ltd. have previously availed themselves of this forum by submitting to the jurisdiction of this court and asserting counterclaims in this judicial district. *See Novartis Pharmaceuticals Corp. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-157-LPS (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 15-179-GMS (D. Del.); *Allos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al.*, C.A. No. 14-778-RGA (D. Del.); *Genzyme Corporation et al. v. Dr. Reddy's Laboratories Ltd. et al.*, C.A. No. 13-1506-GMS (D. Del.); *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 15-306-GMS (D. Del.); *Teijin Ltd. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 13-1780-SLR (D. Del.); and *Pfizer Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 13-989-SLR (D. Del.).

21. Alternatively, assuming that the above facts do not establish personal jurisdiction over DRL, Ltd., this Court may exercise jurisdiction over DRL, Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) DRL, Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) DRL, Ltd. has sufficient contacts with the United States as a whole, including but not limited to acting in concert with DRL, Inc. to prepare and submit an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over DRL, Ltd. satisfies due process.

## **FACTUAL BACKGROUND**

### **A. The '894 Patent**

22. On January 7, 2003, the '894 Patent was duly and legally issued to Unimed Pharmaceuticals, Inc., and Laboratoires Besins-Iscovesco as co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '894 Patent is attached as Exhibit A to this Complaint.

23. In 2007, Unimed Pharmaceuticals, Inc. changed its name to Unimed Pharmaceuticals, LLC.

24. In 2004, Laboratoires Besins-Iscovesco changed its name to Besins-Iscovesco U.S., Inc. In 2008, Besins-Iscovesco U.S., Inc. changed its name to Besins Healthcare Inc.

25. Unimed Pharmaceuticals, LLC and Besins Healthcare Inc. are the owners of all right, title, and interest in the '894 Patent.

26. The expiration date of the '894 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the "Orange Book") is August 30, 2020.

### **B. The '136 Patent**

27. On June 18, 2013, the '136 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '136 Patent is attached as Exhibit B to this Complaint.

28. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '136 Patent to Besins Healthcare Luxembourg SARL.

29. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '136 Patent.

30. The expiration date of the '136 Patent listed in the Orange Book is October 12, 2026.

**C. The '137 Patent**

31. On June 18, 2013, the '137 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '137 Patent is attached as Exhibit C to this Complaint.

32. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '137 Patent to Besins Healthcare Luxembourg SARL.

33. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '137 Patent.

34. The expiration date of the '137 Patent listed in the Orange Book is October 12, 2026.

**D. The '138 Patent**

35. On June 18, 2013, the '138 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '138 Patent is attached as Exhibit D to this Complaint.

36. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '138 Patent to Besins Healthcare Luxembourg SARL.

37. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '138 patent.

38. The expiration date of the '138 Patent listed in the Orange Book is October 12, 2026.

**E. The '925 Patent**

39. On July 16, 2013, the '925 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Laboratoires Besins International, SAS, as co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '925 Patent is attached as Exhibit E to this Complaint.

40. On November 21, 2013, Laboratoires Besins International, SAS assigned its interest in the '925 Patent to Besins Healthcare Luxembourg SARL.

41. Unimed Pharmaceuticals, LLC and Besins Healthcare Luxembourg SARL, are the owners of all right, title, and interest in the '925 Patent.

42. The expiration date of the '925 Patent listed in the Orange Book is October 12, 2026.

**F. The '057 Patent**

43. On May 20, 2014, the '057 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '057 Patent is attached as Exhibit F to this Complaint.

44. The expiration date of the '057 Patent listed in the Orange Book is October 12, 2026.



**G. The '881 Patent**

45. On June 3, 2014, the '881 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '881 Patent is attached as Exhibit G to this Complaint.

46. The expiration date of the '881 Patent listed in the Orange Book is October 12, 2026.

**H. The '070 Patent**

47. On June 17, 2014, the '070 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '070 Patent is attached as Exhibit H to this Complaint.

48. The expiration date of the '070 Patent listed in the Orange Book is October 12, 2026.

**I. The '329 Patent**

49. On June 24, 2014, the '329 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Luxembourg SARL as co-applicants and co-assignees. The inventors are Ramana Malladi and Jodi Stahlman. A true and correct copy of the '329 Patent is attached as Exhibit I to this Complaint.

50. The expiration date of the '329 Patent listed in the Orange Book is October 12, 2026.

**J. The '816 Patent**

51. On September 8, 2015, the '816 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Inc. as co-applicants and co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '816 Patent is attached as Exhibit J to this Complaint.

52. The expiration date of the '816 Patent listed in the Orange Book is August 30, 2020.

**K. The '089 Patent**

53. On September 15, 2015, the '089 Patent was duly and legally issued to Unimed Pharmaceuticals, LLC, and Besins Healthcare Inc. as co-applicants and co-assignees. The inventors are Robert E. Dudley and Dominique Drouin. A true and correct copy of the '089 Patent is attached as Exhibit K to this Complaint.

54. The expiration date of the '089 Patent listed in the Orange Book is August 30, 2020.

**L. AndroGel®**

55. AbbVie is the registered holder of approved NDA No. 22-309 for the manufacture and sale of testosterone gel, 1.62%, a prescription medicine used to treat adult males for conditions associated with a deficiency or absence of endogenous testosterone. AbbVie markets and sells testosterone gel, 1.62% in the United States under the trade name AndroGel®. AndroGel® 1.62% was approved by the FDA on April 29, 2011.

56. The '894 Patent is listed in the Orange Book in conjunction with AndroGel® (testosterone gel) 1.62%, and the claims of the '894 Patent cover that product.

57. The '136 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '136 Patent cover that product.

58. The '137 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '137 Patent cover that product.

59. The '138 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '138 Patent cover that product.

60. The '925 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '925 Patent cover that product.

61. The '057 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '057 Patent cover that product.

62. The '881 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '881 Patent cover that product.

63. The '070 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '070 Patent cover that product.

64. The '329 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '329 Patent cover that product.

65. The '816 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '816 Patent cover that product.

66. The '089 Patent is listed in the Orange Book in conjunction with AndroGel<sup>®</sup> (testosterone gel) 1.62%, and the claims of the '089 Patent cover that product.

**M. Infringement by DRL**

67. On information and belief, DRL, Inc., in concert with and on behalf of DRL, Ltd., submitted ANDA No. 208620 to the FDA under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to market DRL's Generic AndroGel<sup>®</sup> prior to the expiration date of the patents-in-suit.

68. On information and belief, DRL, Inc. and DRL, Ltd. intend to engage in commercial manufacture, use, sale, offer for sale, or importation into the U.S. of DRL's Generic AndroGel<sup>®</sup> promptly upon receiving FDA approval to do so.

69. Plaintiffs received the Notice Letter signed on behalf of DRL, Inc. and DRL, Ltd. stating that ANDA No. 208620 includes a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, sale or importation of DRL's Generic AndroGel<sup>®</sup> before the expiration of the patents-in-suit. In the Notice Letter, DRL also states that, "[the patents-in-suit] are invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer to sell or importation into the United States of DRL's testosterone gel product for which DRL has submitted its application."

70. On information and belief, the submission of ANDA No. 208620 to the FDA constitutes infringement by DRL, Inc. and DRL, Ltd. of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic AndroGel<sup>®</sup> would infringe the patents-in-suit under 35 U.S.C. § 271(a)–(c).

71. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

### **CLAIMS FOR RELIEF**

#### **COUNT I**

#### **(DIRECT INFRINGEMENT OF U.S. PATENT NO. 6,503,894)**

72. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 71 above as though fully restated herein.

73. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '894 Patent by Defendants.

74. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> and the use thereof will infringe the '894 Patent under 35 U.S.C. § 271(a).

75. Unless Defendants are enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Defendants' infringement of the '894 Patent. Unimed and Besins do not have an adequate remedy at law.

76. Defendants' infringement of the '894 Patent is willful and made with knowledge of the '894 Patent.

**COUNT II**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 6,503,894)**

77. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 76 above as though fully restated herein.

78. Defendants have knowledge of the '894 Patent.

79. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '894 patent.

80. The use of DRL's Generic AndroGel<sup>®</sup> by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '894 patent.

81. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '894 patent.

82. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

83. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '894 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '894 patent.

84. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

85. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '894 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '894 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT III**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 6,503,894)**

86. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 85 above as though fully restated herein.

87. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

88. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '894 patent.

89. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '894 patent.

90. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT IV**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 6,503,894)**

91. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 90 above as though fully restated herein.

92. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '894 patent.

93. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

94. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '894 Patent under 35 U.S.C. § 271(a)–(c).

95. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '894 Patent.

96. There is a justiciable case or controversy between Unimed and Besins and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or

importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '894 Patent.

97. If Defendants' infringement of the '894 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT V**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,466,136)**

98. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 97 above as though fully restated herein.

99. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '136 Patent by Defendants.

100. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> will infringe the '136 Patent under 35 U.S.C. § 271(a).

101. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '136 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

102. Defendants' infringement of the '136 Patent is willful and made with knowledge of the '136 Patent.

**COUNT VI**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,136)**

103. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 102 above as though fully restated herein.

104. Defendants have knowledge of the '136 Patent.



105. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '136 patent.

106. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '136 patent.

107. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '136 patent.

108. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '136 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '136 patent.

109. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

110. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '136 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '136 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT VII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,136)**

111. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 110 above as though fully restated herein.

112. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

113. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '136 patent.

114. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '136 patent.

115. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT VIII**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,136)**

116. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 115 above as though fully restated herein.

117. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '136 Patent.

118. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

119. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '136 Patent under 35 U.S.C. § 271(a)–(c).

120. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '136 Patent.

121. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '136 Patent.

122. If Defendants' infringement of the '136 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT IX**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,466,137)**

123. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 122 above as though fully restated herein.

124. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '137 Patent by Defendants.

125. If allowed on the market, the use of DRL's Generic AndroGel<sup>®</sup> will infringe the '137 Patent under 35 U.S.C. § 271(a).

126. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '137 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

127. Defendants' infringement of the '137 Patent is willful and made with knowledge of the '137 Patent.

**COUNT X**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,137)**

128. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 127 above as though fully restated herein.

129. Defendants have knowledge of the '137 Patent.

130. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '137 patent.

131. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '137 patent.

132. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '137 patent.

133. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

134. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '137 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '137 patent.

135. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

136. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '137 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '137 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XI**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,137)**

137. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 136 above as though fully restated herein.

138. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

139. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '137 patent.

140. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '137 patent.

141. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XII**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,137)**

142. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 141 above as though fully restated herein.

143. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '137 Patent.

144. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

145. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '137 Patent under 35 U.S.C. § 271(a)–(c).

146. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '137 Patent.

147. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '137 Patent.

148. If Defendants' infringement of the '137 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XIII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,466,138)**

149. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 148 above as though fully restated herein.

150. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '138 Patent by Defendants.

151. If allowed on the market, the use of DRL's Generic AndroGel<sup>®</sup> will infringe the '138 Patent under 35 U.S.C. § 271(a).

152. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '138 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

153. Defendants' infringement of the '138 Patent is willful and made with knowledge of the '138 Patent.

**COUNT XIV**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,466,138)**

154. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 153 above as though fully restated herein.

155. Defendants have knowledge of the '138 Patent.

156. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '138 patent.

157. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '138 patent.

158. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '138 patent.

159. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

160. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '138 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '138 patent.

161. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

162. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '138 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '138 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XV**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,466,138)**

163. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 162 above as though fully restated herein.

164. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.



165. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '138 patent.

166. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '138 patent.

167. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XVI**

**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,466,138)**

168. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 167 above as though fully restated herein.

169. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '138 patent.

170. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

171. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '138 Patent under 35 U.S.C. § 271(a)–(c).

172. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '138 Patent.

173. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale,

offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '138 Patent.

174. If Defendants' infringement of the '138 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XVII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,486,925)**

175. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 174 above as though fully restated herein.

176. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '925 Patent by Defendants.

177. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> will infringe the '925 Patent under 35 U.S.C. § 271(a).

178. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '925 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

179. Defendants' infringement of the '925 Patent is willful and made with knowledge of the '925 Patent.

**COUNT XVIII**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,486,925)**

180. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 179 above as though fully restated herein.

181. Defendants have knowledge of the '925 Patent.

182. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '925 patent.

183. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '925 patent.

184. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '925 patent.

185. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '925 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '925 patent.

186. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

187. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '925 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '925 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XIX**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,486,925)**

188. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 187 above as though fully restated herein.

189. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel®.

190. DRL's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '925 patent.

191. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel® is especially adapted for a use that infringes the '925 patent.

192. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel®.

**COUNT XX**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,486,925)**

193. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 192 above as though fully restated herein.

194. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel® prior to expiration of the '925 patent.

195. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

196. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '925 Patent under 35 U.S.C. § 271(a)–(c).

197. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '925 Patent.

198. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '925 Patent.

199. If Defendants' infringement of the '925 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXI**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,729,057)**

200. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 199 above as though fully restated herein.

201. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '057 Patent by Defendants.

202. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> will infringe the '057 Patent under 35 U.S.C. § 271(a).

203. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '057 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

204. Defendants' infringement of the '057 Patent is willful and made with knowledge of the '057 Patent.

**COUNT XXII**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,729,057)**

205. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 204 above as though fully restated herein.

206. Defendants have knowledge of the '057 Patent.

207. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '057 patent.

208. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '057 patent.

209. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '057 patent.

210. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '057 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '057 patent.

211. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

212. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that

directly infringes one or more claims of the '057 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '057 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XXIII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,729,057)**

213. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 212 above as though fully restated herein.

214. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel®.

215. DRL's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '057 patent.

216. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel® is especially adapted for a use that infringes the '057 patent.

217. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel®.

**COUNT XXIV**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,729,057)**

218. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 217 above as though fully restated herein.

219. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel® prior to expiration of the '057 patent.

220. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United

States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

221. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '057 Patent under 35 U.S.C. § 271(a)–(c).

222. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '057 Patent.

223. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '057 Patent.

224. If Defendants' infringement of the '057 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXV**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,741,881)**

225. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 224 above as though fully restated herein.

226. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '881 Patent by Defendants.

227. If allowed on the market, the use of DRL's Generic AndroGel<sup>®</sup> will infringe the '881 Patent under 35 U.S.C. § 271(a).



228. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '881 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

229. Defendants' infringement of the '881 Patent is willful and made with knowledge of the '881 Patent.

**COUNT XXVI**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,741,881)**

230. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 229 above as though fully restated herein.

231. Defendants have knowledge of the '881 Patent.

232. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '881 patent.

233. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '881 patent.

234. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '881 patent.

235. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

236. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '881 patent. Since at least the date of the Notice Letter, Defendants have acted

with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '881 patent.

237. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

238. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '881 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '881 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XXVII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,741,881)**

239. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 238 above as though fully restated herein.

240. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

241. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '881 patent.

242. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '881 patent.

243. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XXVIII**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,741,881)**

244. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 243 above as though fully restated herein.

245. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '881 Patent.

246. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

247. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '881 Patent under 35 U.S.C. § 271(a)–(c).

248. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '881 Patent.

249. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '881 Patent.

250. If Defendants' infringement of the '881 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXIX**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,754,070)**

251. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 250 above as though fully restated herein.

252. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '070 Patent by Defendants.

253. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> will infringe the '070 Patent under 35 U.S.C. § 271(a).

254. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '070 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

255. Defendants' infringement of the '070 Patent is willful and made with knowledge of the '070 Patent.

**COUNT XXX**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,754,070)**

256. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 255 above as though fully restated herein.

257. Defendants have knowledge of the '070 Patent.

258. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '070 patent.

259. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '070 patent.

260. Defendants' proposed label for DRL's Generic AndroGel® will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel® in a manner that will directly infringe one or more claims of the '070 patent.

261. If DRL's Generic AndroGel® is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '070 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '070 patent.

262. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

263. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel® in a manner that directly infringes one or more claims of the '070 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '070 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XXXI**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,754,070)**

264. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 263 above as though fully restated herein.

265. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel®.

266. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '070 patent.

267. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '070 patent.

268. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XXXII**

**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,754,070)**

269. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 268 above as though fully restated herein.

270. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '070 Patent.

271. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

272. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '070 Patent under 35 U.S.C. § 271(a)–(c).

273. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '070 Patent.

274. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale,

offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '070 Patent.

275. If Defendants' infringement of the '070 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXXIII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,759,329)**

276. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 275 above as though fully restated herein.

277. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '329 Patent by Defendants.

278. If allowed on the market, DRL's Generic AndroGel<sup>®</sup> will infringe the '329 Patent under 35 U.S.C. § 271(a).

279. Unless Defendants are enjoined by the Court, Unimed and Besins Luxembourg will be substantially and irreparably harmed by Defendants' infringement of the '329 Patent. Unimed and Besins Luxembourg do not have an adequate remedy at law.

280. Defendants' infringement of the '329 Patent is willful and made with knowledge of the '329 Patent.

**COUNT XXXIV**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 8,759,329)**

281. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 280 above as though fully restated herein.

282. Defendants have knowledge of the '329 Patent.

283. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '329 patent.

284. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '329 patent.

285. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '329 patent.

286. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '329 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '329 patent.

287. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

288. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '329 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '329 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.



**COUNT XXXV**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 8,759,329)**

289. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 288 above as though fully restated herein.

290. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel®.

291. DRL's Generic AndroGel® constitutes a material part of the inventions covered by the claims of the '329 patent.

292. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel® is especially adapted for a use that infringes the '329 patent.

293. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel®.

**COUNT XXXVI**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 8,759,329)**

294. Unimed and Besins Luxembourg incorporate by reference and reallege paragraphs 1 through 293 above as though fully restated herein.

295. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel® prior to expiration of the '329 patent.

296. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel® upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

297. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '329 Patent under 35 U.S.C. § 271(a)–(c).

298. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '329 Patent.

299. There is a justiciable case or controversy between Unimed and Besins Luxembourg and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '329 Patent.

300. If Defendants' infringement of the '329 Patent is not enjoined, Unimed and Besins Luxembourg will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXXVII**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,125,816)**

301. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 300 above as though fully restated herein.

302. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '816 Patent by Defendants.

303. If allowed on the market, the use of DRL's Generic AndroGel<sup>®</sup> will infringe the '816 Patent under 35 U.S.C. § 271(a).

304. Unless Defendants are enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Defendants' infringement of the '816 Patent. Unimed and Besins do not have an adequate remedy at law.

305. Defendants' infringement of the '816 Patent is willful and made with knowledge of the '816 Patent.

**COUNT XXXVIII**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 9,125,816)**

306. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 305 above as though fully restated herein.

307. Defendants have knowledge of the '816 Patent.

308. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '816 patent.

309. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '816 patent.

310. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '816 patent.

311. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

312. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '816 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '816 patent.

313. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

314. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '816 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '816 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XXXIX**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 9,125,816)**

315. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 314 above as though fully restated herein.

316. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

317. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '816 patent.

318. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '816 patent.

319. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XL**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 9,125,816)**

320. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 319 above as though fully restated herein.

321. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '816 patent.

322. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

323. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '816 Patent under 35 U.S.C. § 271(a)–(c).

324. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants will dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '816 Patent.

325. There is a justiciable case or controversy between Unimed and Besins and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '816 Patent.

326. If Defendants' infringement of the '816 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XLI**  
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,132,089)**

327. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 326 above as though fully restated herein.

328. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 208620 to the FDA seeking approval of DRL's Generic AndroGel<sup>®</sup> was an act of infringement of the '089 Patent by Defendants.

329. If allowed on the market, the use of DRL's Generic AndroGel<sup>®</sup> will infringe the '089 Patent under 35 U.S.C. § 271(a).

330. Unless Defendants are enjoined by the Court, Unimed and Besins will be substantially and irreparably harmed by Defendants' infringement of the '089 Patent. Unimed and Besins do not have an adequate remedy at law.

331. Defendants' infringement of the '089 Patent is willful and made with knowledge of the '089 Patent.

**COUNT XLII**  
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 9,132,089)**

332. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 331 above as though fully restated herein.

333. Defendants have knowledge of the '089 Patent.

334. The use of DRL's Generic AndroGel<sup>®</sup> is covered by one or more claims of the '089 patent.

335. The use of DRL's Generic AndroGel<sup>®</sup> by any Healthcare Providers and patients, will directly infringe one or more claims of the '089 patent.

336. Defendants' proposed label for DRL's Generic AndroGel<sup>®</sup> will explicitly instruct Healthcare Providers and patients to use DRL's Generic AndroGel<sup>®</sup> in a manner that will directly infringe one or more claims of the '089 patent.

337. Any use of DRL's Generic AndroGel<sup>®</sup> by patients will be performed at the direction and control of Health Care Providers treating hypogonadism, who in turn are instructed by Defendants in their proposed label for DRL's Generic AndroGel<sup>®</sup>.

338. If DRL's Generic AndroGel<sup>®</sup> is approved by the FDA, Defendants will actively induce others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '089 patent. Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness, of the fact that the induced acts would constitute infringement of the '089 patent.

339. Defendants intend to cause direct infringement by others, e.g. Healthcare Providers and patients.

340. Upon FDA approval of ANDA No. 208620, Defendants will take affirmative steps to induce infringement by, among other things, instructing Healthcare Providers and patients, through Defendants' proposed label, to use DRL's Generic AndroGel<sup>®</sup> in a manner that directly infringes one or more claims of the '089 patent. Thus, Defendants will aid, abet, urge, or encourage others including, e.g., Healthcare Providers and patients, to directly infringe one or more claims of the '089 patent, and Defendants will affirmatively and specifically intend to cause direct infringement.

**COUNT XLIII**  
**(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 9,132,089)**

341. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 340 above as though fully restated herein.

342. If ANDA No. 208620 is approved, Defendants intend to and will offer to sell, sell, or import into the United States DRL's Generic AndroGel<sup>®</sup>.

343. DRL's Generic AndroGel<sup>®</sup> constitutes a material part of the inventions covered by the claims of the '089 patent.

344. On information and belief, Defendants have had and continue to have knowledge that DRL's Generic AndroGel<sup>®</sup> is especially adapted for a use that infringes the '089 patent.

345. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for DRL's Generic AndroGel<sup>®</sup>.

**COUNT XLIV**  
**(DECLARATORY JUDGMENT AS TO U.S. PATENT NO. 9,132,089)**

346. Unimed and Besins incorporate by reference and reallege paragraphs 1 through 345 above as though fully restated herein.

347. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import DRL's Generic AndroGel<sup>®</sup> prior to expiration of the '089 patent.

348. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of DRL's Generic AndroGel<sup>®</sup> upon receipt of final FDA approval of ANDA No. 208620, unless enjoined by the Court.

349. On information and belief, Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of DRL's Generic AndroGel<sup>®</sup> will constitute infringement of the '089 Patent under 35 U.S.C. § 271(a)–(c).

350. On information and belief, based on positions taken by DRL in the Notice Letter, Defendants will dispute that DRL's Generic AndroGel<sup>®</sup> infringes any valid claim of the '089 Patent.



351. There is a justiciable case or controversy between Unimed and Besins and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL's Generic AndroGel<sup>®</sup> according to ANDA No. 208620 will infringe one or more claims of the '089 Patent.

352. If Defendants' infringement of the '089 Patent is not enjoined, Unimed and Besins will suffer substantial and irreparable harm from which there is no remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. For a declaration that Defendants have infringed the patents-in-suit;
- B. For a declaration that the commercial use, sale, offer for sale, manufacture, and importation by Defendants of DRL's Generic AndroGel<sup>®</sup> will infringe the patents-in-suit;
- C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of ANDA No. 208620 be no earlier than the expiration date of the last to expire of the patents-in-suit, including any extensions or adjustments;
- D. For an order enjoining Defendants and their affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the patents-in-suit;
- E. For a determination that Defendants' infringement is willful;
- F. For a determination that this is an exceptional case under 35 U.S.C. § 285; and
- G. For such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

Mary B. Graham (#2256)  
Stephen J. Kraftschik  
1201 N. Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
mgraham@mnat.com  
skraftschik@mnat.com

*Attorneys for Unimed Pharmaceuticals, LLC,  
Besins Healthcare Inc., and Besins Healthcare  
Luxembourg SARL*

OF COUNSEL:

Calvin P. Griffith  
JONES DAY  
North Point  
901 Lakeside Ave.  
Cleveland, OH 44114

Jason G. Winchester  
JONES DAY  
77 W. Wacker Dr.  
Chicago, IL 60601

Gasper J. La Rosa  
Kenneth S. Canfield  
JONES DAY  
222 E. 41st St.  
New York, NY 10017  
*Attorneys for Unimed  
Pharmaceuticals, LLC*

Liane M. Peterson  
Andrew R. Cheslock  
FOLEY & LARDNER LLP  
3000 K Street, N.W., Suite 600  
Washington, DC 20007-5109  
*Attorneys for Besins Healthcare Inc. and  
Besins Healthcare Luxembourg SARL*

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